SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Judiciary Committee

BILL:	CS/SB 1310
INTRODUCER:	Health Care Committee and Senator Clary
SUBJECT:	Cancer Drug Donation Program
DATE:	April 24, 2006 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HE	**Fav/CS**
2.	Luczynski	Maclure	JU	**Pre-meeting**
3.				
4.				
5.				
6.				

I. Summary:

The bill creates the "Cancer Drug Donation Program Act" (act) and establishes the Cancer Drug Donation Program within the Department of Health (DOH). The bill provides definitions, specifies requirements for the program, and requires DOH to adopt rules covering: standards and procedures for participants that accept, store, distribute, or dispense donated cancer drugs or supplies; necessary forms for administration of the program; a maximum handling fee that may be charged by a participant that accepts and distributes or dispenses cancer drugs or supplies; categories of cancer drugs and supplies that the program will accept for dispensing; and maintenance and distribution of the participant registry.

Under the bill, a pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under this act, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

This bill creates section 381.94, Florida Statutes.

II. Present Situation:

Cancer

Cancer is the second leading cause of death in the United States.[1] As of January 1, 2002, an estimated 10.1 million Americans are living with a previous diagnosis of cancer.[2] According to

[1] Ctrs. for Disease Control & Prevention, Dep't of Health & Human Servs., *Cancer*, *at* http://www.cdc.gov/node.do/id/0900f3ec80193c0d (last visited Apr. 17, 2006).

the Centers for Disease Control and Prevention, in 2005, approximately 1,372,910 Americans will receive a new diagnosis of cancer.[3] Cancer develops when cells in a part of the body begin to grow out of control.[4] Although there are many kinds of cancer, they all start because of out-of-control growth of abnormal cells. Normal body cells grow, divide, and die in an orderly fashion. During the early years of a person's life, normal cells divide more rapidly until the person becomes an adult. After that, cells in most parts of the body divide only to replace worn-out or dying cells and to repair injuries. Cancer cells continue to grow and divide and are different from normal cells. Instead of dying, they outlive normal cells and continue to form new abnormal cells. Cancer cells develop because of damage to DNA.[5] This substance is in every cell and directs all activities. Most of the time when DNA becomes damaged the body is able to repair it. In cancer cells, the damaged DNA is not repaired.

Chemotherapy is treatment with powerful medicines that are most often given by mouth or by injection. Unlike radiation therapy or surgery, chemotherapy drugs can treat cancers that have spread throughout the body, because they travel throughout the body in the bloodstream. Often, a combination of chemotherapy is used instead of a single drug. Chemotherapy is given in cycles, each followed by a recovery period. The total course of chemotherapy is often about six months, usually ranging from three to nine months. After a cancer is removed by surgery, chemotherapy can significantly reduce the risk of cancer returning. The chances of cancer returning and the potential benefit of chemotherapy depend on the type of cancer and other individual factors.

The Florida Drug and Cosmetic Act

The Florida Drug and Cosmetic Act is codified at ss. 499.001 – 499.081, F.S. The Act defines "wholesale distribution" to mean distribution of prescription drugs to persons other than a consumer or patient, but does not include specified activities.[6] Under s. 499.012, F.S., the activities exempt from "wholesale distribution" include: purchases or acquisitions by a hospital or other health care entity of prescription drugs for its own use from a group purchasing organization of which it is a member; the sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization; the sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control; the sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or entity eligible to purchase prescription drugs at public health service prices under federal law to a contract provider or its subcontractor for eligible patients under specified conditions; and certain activities conducted in accordance with rules of the Department of Health (DOH).

Under s. 499.005, F.S., acts that are unlawful for a person to perform or cause to perform include the following:

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[2] Ctrs. for Disease Control & Prevention, Dep't of Health & Human Servs., *United States Cancer Statistics: 2002 Incidence & Mortality* 1, http://www.cdc.gov/cancer/npcr/uscs/pdf/2002_USCS.pdf (last visited Apr. 17, 2006).
[3] *Id.*
[4] The American Cancer Society, Detailed Guide: What Is Cancer?, http://www.cancer.org/docroot/CRI/content/CRI_2_4_1x_What_Is_Cancer.asp?sitearea= (last visited Apr. 17, 2006).
[5] *Id.*
[6] Section 499.012(1)(a), F.S.

- The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use;
- The adulteration or misbranding of any drug, device, or cosmetic;
- The receipt of any drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery of such drug, device, or cosmetic, for pay or otherwise;
- The sale, distribution, purchase, trade, holding, or offering of any drug, device, or cosmetic in violation of the Florida Drug and Cosmetic Act;
- Committing any act that causes a drug, device, or cosmetic to be a counterfeit drug, device, or cosmetic; or selling, dispensing, or holding for sale a counterfeit drug, device, or cosmetic;
- The possession of any drug in violation of the Florida Drug and Cosmetic Act.
- The purchase or receipt of a legend drug from a person that is not authorized under ch. 499, F.S., to distribute legend drugs to that purchaser or recipient;
- The sale or transfer of a legend drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess legend drugs from the person selling or transferring the legend drug;
- Obtaining or attempting to obtain a prescription drug or device by fraud, deceit, misrepresentation or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug or device;
- Removing a pharmacy's dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug; and
- Distributing a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in ch. 465, F.S., the Florida Pharmacy Act, or the rules adopted under ch. 465, F.S.

Section 499.0051, F.S., specifies criminal acts involving contraband or adulterated drugs. A "contraband legend drug" means any adulterated drug, as defined in s. 499.006, F.S., any counterfeit drug, as defined in s. 499.003, F.S.,[7] and also means any legend drug for which a pedigree paper does not exist, or for which the pedigree paper in existence has been forged, counterfeited, falsely created, or contains any altered, false, or misrepresented matter.[8] Under subsection 499.0051(4), F.S., a person who knowingly purchases or receives from a person not authorized to distribute legend drugs under ch. 499, F.S., a legend drug in a wholesale distribution transaction commits a second degree-felony, which is punishable by imprisonment of up to 15 years and a fine of up to $ 10,000. A person who knowingly sells or transfers to a person not authorized to purchase or possess legend drugs, under the law of the jurisdiction in which the person receives the drug, a legend drug in a wholesale distribution transaction commits a second-degree felony.[9] A person who is knowingly in actual or constructive

[7] Section 499.003(12), F.S., defines "counterfeit drug, counterfeit device, or counterfeit cosmetic" to mean a drug, device, or cosmetic which, or the container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug, device, or cosmetic manufacturer, processor, packer, or distributor other than the person that in fact manufactured, processed, packed, or distributed that drug, device, or cosmetic and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, that other drug, device, or cosmetic manufacturer, processor, packer, or distributor.
[8] Section 499.003(10), F.S.
[9] Section 499.0051(5), F.S.

possession of any amount of contraband legend drugs, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of contraband legend drugs, commits a second-degree felony.[10] A person who knowingly sells, purchases, manufactures, delivers, or brings into Florida, or who is knowingly in actual or constructive possession of any amount of contraband legend drugs valued at $25,000 or more commits a first-degree felony punishable by imprisonment of up to 30 years and the imposition of a fine of up to $10,000.[11]

Regulation of Pharmacy

Chapter 465, F.S., governs the regulation of the practice of pharmacy by the Board of Pharmacy in DOH. Section 465.019(2)(b), F.S., provides requirements for institutional pharmacies. "Class II institutional pharmacies" are those institutional pharmacies that employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, shall provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution.

Section 465.015(2)(c), F.S., makes it unlawful for a pharmacist to sell or dispense drugs without first being furnished with a prescription. Section 465.016(1)(l), F.S., prohibits a pharmacy from placing into stock any part of any prescription compounded or dispensed which is returned by the patient. Additionally, the Board of Pharmacy has adopted an administrative rule that prohibits a pharmacist from placing into the stock of any pharmacy, any part of any prescription compounded or dispensed, which is returned by a patient, except as specified in the Board of Pharmacy rules.[12] The exception is that in a closed drug delivery system in which unit-dose medication is dispensed to in-patients, the unused unit dose of medication may be returned to the pharmacy for redispensing only if each dose is individually sealed and if each unit dose or the unit-dose system of which it is clearly a part, is labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date.[13] A "closed drug delivery system" means a system in which control of the unit-dose medication is maintained by the facility rather than by the individual patient. A "unit-dose system" means a system in which all individually sealed unit doses are physically connected as a unit.[14]

Subsection (4) of section 400.141, F.S., requires a pharmacist under contract with a nursing home to repackage a nursing facility resident's bulk prescription medication which has been packaged by another pharmacist into a unit-dose system compatible with the system used by the nursing facility, if the pharmacist is requested to offer such service. Such repackaging services must be made available to residents with bulk prescription medication benefits covered under a qualified pension plan, as provided for under specified federal law, or a long-term-care policy, as defined under specified state law. A pharmacist who correctly repackages and relabels the medication and the nursing home that correctly administers such repackaged medication are shielded from liability in any civil or administrative action arising from the repackaging. To qualify for the repackaging service, a nursing home resident must sign an informed-consent form provided by the facility which includes an explanation of the repackaging process and which

[10] Section 499.0051(6), F.S.
[11] Section 499.0052, F.S.
[12] Fla. Admin. Code R. Rule 64B16-28.118 (2006).
[13] Fla. Admin. Code R. Rule 64B16-28.118(1) (2006).
[14] Fla. Admin. Code R. Rule 64B16-28.118(5) (2006).

notifies the resident that the facility is immune from liability. A pharmacist who repackages and relabels prescriptions for use in a unit-dose system in a nursing home may charge a reasonable fee for costs to do so.

III. Effect of Proposed Changes:

The bill creates the "Cancer Drug Donation Program Act" (act) within s. 381.94, F.S. A cancer drug donation program is created within the Department of Health (DOH) for the purpose of authorizing and facilitating the donation of cancer drugs and supplies to eligible patients.

The bill provides the following definitions for use in the act.

- "Cancer drug" is defined to mean a prescription drug that has been approved by the Federal Food, Drug, and Cosmetic Act and is used to treat cancer or its side effects or used to treat the side effects of a prescription drug used to treat cancer or its side effects. "Cancer drug" does not include any controlled substance.
- "Closed drug delivery system" means a system in which the actual control of the unit-dose medication package is maintained by the facility rather than by the individual patient.
- "Department" means the Department of Health.
- "Donor" means a patient or patient representative who donates cancer drugs or supplies needed to administer cancer drugs that have been maintained within a closed drug delivery system; health care facilities, nursing homes, hospices, or hospitals with closed drug delivery systems; or pharmacies, drug manufacturers, medical device manufacturers or suppliers; or wholesalers of drugs or supplies, in accordance with the act. "Donor" also includes a Florida-licensed medical or osteopathic physician who receives cancer drugs or supplies directly from a manufacturer, drug wholesaler, or pharmacy.
- "Eligible patient" means a person who is a Florida resident, has a diagnosis of cancer from a Florida-licensed medical or osteopathic physician, holds a valid prescription for a cancer drug, and is not otherwise deemed ineligible to receive a cancer drug.
- "Health care facility" means a Florida-licensed hospital, ambulatory surgical center, or mobile surgical facility.
- "Health care clinic" means a health care clinic licensed under part XIII of chapter 400, F.S.
- "Hospice" means a corporation licensed under part VI of chapter 400, F.S.
- "Hospital" means a facility licensed as a Florida hospital.
- "Nursing home" means a facility licensed as a Florida nursing home.
- "Participant facility" means a class II hospital pharmacy that has elected to participate in the program and that accepts donated cancer drugs and supplies under rules adopted by DOH for the program.
- "Pharmacy" and "pharmacist" means Florida licensed pharmacies and pharmacists.
- "Prescribing practitioner" means a Florida-licensed medical physician or any other medical professional authorized under Florida law to prescribe cancer medication.

- "Prescription drug" means a drug defined in s. 465.003(8), F.S.[15]
- "Program" means the Cancer Drug Donation Program.
- "Supplies" means any supplies used in the administration of a cancer drug.

Any donor is authorized to donate cancer drugs or supplies to a participant facility that elects to participate in the program and agrees to comply with requirements of the bill and rules established by DOH for participation. Cancer drugs or supplies may not be donated to a specific cancer patient, and donated drugs or supplies may not be resold by the program. A participant facility may provide dispensing and consulting services to individuals who are not patients of the hospital. The cancer drug or supplies donated to the program may be prescribed only by a prescribing practitioner for use by an eligible patient and may be dispensed only by a pharmacist.

A cancer drug may only be accepted or dispensed under the program if the drug is in its original, unopened, sealed container, or in a tamper-evident unit-dose packaging, except that a cancer drug packaged in single doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened with tamper-resistant packaging intact.

A cancer drug may not be accepted or dispensed under the program if it bears an expiration date that is less than six months after the date the drug was donated or if the drug appears to have been tampered with or mislabeled. Prior to being dispensed to an eligible patient, the cancer drug or supplies donated under the program must be inspected by a Florida-licensed pharmacist to determine that the drug and supplies do not appear to have been tampered with or mislabeled.

A dispenser of donated cancer drugs or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated cancer drugs or supplies dispensed to any patient under the program. A third-party payor is not required to provide any reimbursement to a dispenser for donated cancer drugs or supplies dispensed to any patient under the program.

A donation of cancer drugs or supplies may only be made at a participant facility. A participant facility that accepts donated cancer drugs or supplies under the program must comply with all applicable federal and Florida law relating to the storage and dispensing of the donated cancer drugs or supplies. A participant facility that participates in the program may charge a handling fee for to cover the cost of preparation and dispensing of cancer drugs or supplies under the program. The fee must be established in rules adopted by DOH.

Upon the recommendation of the Board of Pharmacy, DOH must adopt rules to carry out the Cancer Drug Donation Program. Initial rules for the program must be adopted no later than 90 days after July 1, 2006. The rules must include: standards and procedures for participants that accept, store, distribute, or dispense donated cancer drugs or supplies; necessary forms for administration of the program; the maximum handling fee that may be charged by a participant that accepts and distributes or dispenses cancer drugs or supplies; categories of cancer drugs and supplies that the program will accept for dispensing (DOH may exclude any drug based on its

[15] Section 465.003(8), F.S., defines "medicinal drugs" or "drugs" to mean those substances or preparations commonly known as "prescription" or "legend" drugs which are required by federal or state law to be dispensed only on a prescription, but shall not include patents or proprietary preparations.

therapeutic effectiveness or high potential for abuse or diversion); and maintenance and distribution of the participant registry.

A person who is eligible to receive cancer drugs or supplies under the state Medicaid program or under any other prescription drug program funded in whole or in part by Florida, by the Federal government, or by a third-party insurer is ineligible to participate in the program unless benefits have been exhausted or a certain cancer drug or supply is not covered. The Department of Health must establish and maintain a participant registry for the program. The participant registry must include the participant's name, address, and telephone number and must identify whether the participant is a physician's office, pharmacy, hospital, hospice, or health care clinic. The department must make the participant registry available to any donor wishing to donate cancer drugs or supplies to the program.

A pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under this act, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

The bill provides that if any conflict exists between the provisions in the bill and those in the Florida Pharmacy Act or the Florida Drug and Cosmetic Act the bill must control the operation of the Cancer Drug Donation Program.

The bill appropriates one full-time equivalent position at the salary of $42,715 and recurring funding from the General Revenue Fund in the sum of $65,308 for fiscal year 2006-2007, for purposes of implementing the Cancer Drug Donation Program created in the bill.

The bill provides an effective date of July 1, 2006.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The bill requires the Department of Health (DOH) to make the participant registry available to any donor wishing to donate cancer drugs or supplies to the program. Without an exemption to the Public Records Law, such records are available to the public.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

D. Other Constitutional Issues:

Access to the Courts

Under the bill, a pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under this act, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug. The bill's extension of immunity for liability to pharmaceutical manufacturers raises questions about possible infringements on the right of access to the courts. Section 21, Art I of the State Constitution provides that the courts shall be open to all for redress for an injury. To impose a barrier or limitation on litigants' right to file certain actions, the bill would have to meet the test announced by the Florida Supreme Court in *Kluger v. White.*[16] Under the constitutional test established by the Florida Supreme Court in *Kluger v. White*, the Legislature would have to: (1) provide a reasonable alternative remedy or commensurate benefit, or (2) make a legislative showing of overpowering public necessity for the abolishment of the right and no alternative method of meeting such public necessity.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

The Department of Health reports that, in order to dispense donated drugs under the bill, hospital pharmacies will need to obtain a community pharmacy permit (the licensure fee is $255).

B. Private Sector Impact:

Program participants may incur costs associated with storage and disposal of donated drugs. Program participants may benefit from the handling fee authorized under the bill. Program drug recipients may directly benefit through any reduced drug treatment costs and access to medications and supplies that they could not otherwise afford to treat their cancer. Because a person who is eligible to receive cancer drugs or supplies under the program is either not covered under an insurance program or has exhausted insurance benefits that person would directly incur the cost of the handling fee authorized under the bill.

C. Government Sector Impact:

The Department of Health will incur costs to implement the Cancer Drug Donation Program established under the bill. The bill appropriates one full-time equivalent position at the salary of $42,715 and recurring funding from the General Revenue Fund in the sum of $65,308 for fiscal year 2006-2007, for purposes of implementing the Cancer Drug Donation Program created in the bill.

[16] See *Kluger v. White*, 281 So.2d 1 (Fla. 1973).

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill authorizes any person or entity to donate cancer drugs or supplies to a participating class II pharmacy in the program. According to officials at DOH, this authorization is inconsistent with ch. 499, F.S., which regulates the wholesale distribution of drugs, and with prohibitions under the regulation of pharmacy for the re-use of dispensed drugs. The bill appears to have contradictory provisions. Subsection 381.94(7)(a), F.S., as created in the bill provides that a participant facility that accepts donated cancer drugs or supplies under the program must comply with all applicable federal and Florida law relating to the storage, distribution, and dispensing of the donated cancer drugs or supplies. Subsection 381.94(12), F.S., as created in the bill states that if any conflict exists between the provision in the bill and provisions in ch. 465, F.S., or ch. 499, F.S., that the provisions of the bill must control the operation of the Cancer Drug Donation Program.

The bill limits the dispensing of cancer drugs donated under the program to pharmacists. Dispensing practitioners other than pharmacists would not be able to dispense donated cancer drugs to patients under the bill.

The bill authorizes *any donor* to donate cancer drugs or supplies to a participant facility. The Department of Health staff indicates that the Cancer Drug Donation Program created under the bill provides an opportunity for the possibility of counterfeit drugs to be received by cancer patients because the donated drugs would not have pedigree papers to trace their distribution from the manufacturer to the end-user, the patient. The bill does not expressly prohibit a donor from using a donation as a trick or scheme to transfer contraband drugs or counterfeit drugs, which is currently outlawed under ch. 499, F.S.

Although the bill prohibits program eligibility for recipients of third-payor benefits who have not exhausted their benefits and excludes use of controlled substances as cancer drugs which may be donated, it is unclear how the program will operate. Cancer patients who are treated with cancer drugs as defined under the bill will typically also have pain management needs, which may require the use of controlled substances.

The bill specifies that if the provisions of the bill are in conflict with the pharmacy practice act, ch. 465, F.S., the provisions of the bill must control the operation of the Cancer Drug Donation Program. Class II hospital pharmacies by law are limited to dispensing and consulting services on the premises to patients of that institution. The bill provides that such pharmacies may provide dispensing and consulting services to individuals who are not patients of the hospital. Although the bill resolves the conflict in favor of the operation of the Cancer Drug Donation Program, the Legislature may wish to consider creating an exception to s. 465.019, F.S., to remove the conflict. The pharmacy practice act prohibits re-dispensing of medications under s. 465.016(1), F.S. Although the bill resolves the conflict created by this prohibition in favor of the operation of the Cancer Drug Donation Program, the Legislature may wish to consider

creating an exception to s. 465.016(1), F.S., for pharmacies and pharmacists that voluntarily agree to participate in the Cancer Drug Donation Program.

It is unclear whether including the definition of health care clinic is still relevant to the bill.

VIII. Summary of Amendments:

None.